K090002 Page 1 of 3



## 5. 510(K) SUMMARY

**DATE:** December 31, 2008

AUG - 7 2009

**OWNER:** Baxter Healthcare Corporation
One Deerfield Parkway
Deerfield, IL 60015

**CONTACT PERSON:** Donna Djinovich, Manager Global Regulatory Affairs
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McGaw Park, IL 60085
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**DEVICE NAME:** ***Trade Name***: Acid Concentrate

**Table 5-1.**
**Product Codes for Baxter's Acid Concentrate**

| | |
|---|---|
| 5M8001A | ACID CONCENTRATE 45X (2.0K, 3.1CA) |
| 5M8002A | ACID CONCENTRATE 45X (2.0K, 2.5CA) |
| 5M8003A | ACID CONCENTRATE 45X (3.0K, 3.0CA) |
| 5M8004A | ACID CONCENTRATE 45X (3.0K, 2.5CA) |
| 5M8005A | ACID CONCENTRATE 45X (2.0K, 2.5CA) |
| 5M8006A | ACID CONCENTRATE 45X (4.0K, 2.5CA) |

***Common Name:*** Dialysate Concentrate for Hemodialysis (liquid or powder).

***Classification Name:*** 21 CFR 876.5820 Hemodialysis System and Accessories.

***Class*** Class II

***Product Code:*** KPO

## PREDICATE DEVICES:

**Table 5-2.**
**Previous 510(k)s**

| Device | Company | Previous 510(k) | Clearance Date |
|---|---|---|---|
| Renal Systems Hemodialysis Concentrate | Renal Systems, Inc. | K792213 | 01/04/1980 |
| Renal Systems Hemodialysis Concentrate | Renal Systems, Inc. | K781967 | 12/07/1978 |
| Rockwell Medical Supply LLC , Hemodialysis Concentrate | Rockwell Medical Supply LLC | K954527 | 03/01/1996 |

## DEVICE DESCRIPTION:

Baxter's Acid Concentrate is used in the preparation of hemodialysis solutions when mixed and proportioned with the appropriate volumes of purified water and bicarbonate concentrate solution. These acid concentrate products are mixed and proportioned in a three-stream hemodialysis machine, in which the acid concentrate is proportioned into one stream, a bicarbonate concentrate solution is proportioned into the second stream, and purified water that meets AAMI Standards is proportioned into the third stream. These three streams are then mixed to prepare a final proportioned hemodialysis solution. The proportioned hemodialysis solution is then heated to body temperature and passed through the dialysis fluid compartment of a hemodialyzer counter-current to the flow of the patient's blood.

**STATEMENT OF INTENDED USE:** Acid Concentrate is intended for use as an acid concentrate in hemodialysis therapy.

**TECHNOLOGICAL CHARACTERISTICS:** Acid Concentrate is substantially equivalent to current on market acid concentrate products from Minntech (Centrisol K792213 & K781967) and Rockwell (RenalPure K954527). Baxter's Acid Concentrate utilizes the same intended use as well as the same chemicals and compositions as the predicate devices.

**ASSESSMENT OF NONCLINICAL DATA:**

Baxter Healthcare conducted a risk assessment according to the requirements of ISO 14971:2003 Medical Devices – Application of Risk Management to Medical Devices. Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet the acceptance criteria, and support that the devices are appropriately designed for their intended use.

**CONCLUSIONS:**

Baxter's Acid Concentrate has been verified against established standards and guidelines for its intended use. Testing demonstrates that the proposed device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Donna Djinovich
Manager, Global Regulatory Affairs
Baxter Healthcare Corporation
Renal Devices
1620 Waukegan Road, MPGR-AL
MCGAW PARK IL 60085

AUG – 7 2009

Re: K090002
Trade/Device Name: Acid Concentrate
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: July 17, 2009
Received: July 21, 2009

Dear Ms. Djinovich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090002



## 4. INDICATIONS FOR USE STATEMENT

**510(k) Number (if known):** K090002

**Device Name:** Acid Concentrate

**Indication(s) for Use:**

Acid Concentrate is indicated for use as acid concentrate in hemodialysis therapy.

| | |
|---|---|
| Prescription Use: ☑ | Over-the-Counter Use: ☐ |
| 21 CFR 801 Subpart D | 21 CFR Subpart C |

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090002